UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

POLLYANNA MONTGOMERY, Plaintiff, v. ETHICON, INC. *et al.*, Defendants.	CAUSE NO. 3:20-CV-915 DRL-MGG

AMENDED OPINION AND ORDER

Ethicon, Inc. developed a transvaginal mesh device (TVT-O) to address stress urinary incontinence in women. This case came from the multidistrict litigation panel with numerous motions, including a summary judgment motion and ten motions to exclude proposed experts under Rule 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). This opinion addresses summary judgment before turning to these other motions because it winnows the case's scope.

Unusual to summary judgment, little time need be spent with the facts today. Pollyanna Montgomery suffered from stress urinary incontinence. After trying several other treatments, she underwent surgery in April 2011 to implant Ethicon's TVT-O device (a TVT obturator system distributed by Gynecare). Dr. Adam Perlmutter conducted the implant surgery. Ms. Montgomery says she learned in early 2013 that the device's polypropylene mesh (called Prolene) oxidized and degraded because of the human body's inflammatory reaction and that the mesh could shrink or contract.

Ethicon contends that the TVT-O has a long development history dating back to the 1960s, with this particular product launched in 2004. Focused primarily on Indiana law and Dr. Perlmutter's testimony, Ethicon requests summary judgment. The company is right that the Indiana Product Liability Act subsumes many of the live claims, but failure to warn and design theories remain under a single IPLA claim for the jury to decide. The court thus grants the summary judgment only in part.

STANDARD

Summary judgment is warranted when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The non-moving party must present the court with evidence on which a reasonable jury could rely to find in his favor. *Beardsall v. CVS Pharmacy, Inc.*, 953 F.3d 969, 972 (7th Cir. 2020). The court must construe all facts in the light most favorable to the non-moving party, view all reasonable inferences in that party's favor, *Bellaver v. Quanex Corp.*, 200 F.3d 485, 491-92 (7th Cir. 2000), and avoid "the temptation to decide which party's version of the facts is more likely true," *Payne v. Pauley*, 337 F.3d 767, 770 (7th Cir. 2003); *see also Joll. v. Valparaiso Comty. Schs.*, 953 F.3d 923, 924 (7th Cir. 2020).

In performing its review, the court "is not to sift through the evidence, pondering the nuances and inconsistencies, and decide whom to believe." *Waldridge v. Am. Hoechst Corp.*, 24 F.3d 918, 920 (7th Cir. 1994). Nor is the court "obliged to research and construct legal arguments for parties." *Nelson v. Napolitano*, 657 F.3d 586, 590 (7th Cir. 2011). Instead, the "court has one task and one task only: to decide, based on the evidence of record, whether there is any material dispute of fact that requires a trial." *Id.* The court must grant a summary judgment motion when no such genuine factual issue—a triable issue—exists under the law. *Luster v. Ill. Dept. of Corrs.*, 652 F.3d 726, 731 (7th Cir. 2011).

DISCUSSION

A. *The Parties Stipulate to Dismiss Counts 2, 9, 11-13, and 15.*

The complaint asserts fifteen claims. The parties stipulate to dismiss six claims. Because this stipulation concerns something less than the entire action, Rule 15 governs rather than Rule 41. *See* Fed. R. Civ. P. 15(a)(2), 41(a). Rule 15 authorizes a pleading's amendment that drops singular parties or claims, *Taylor v. Brown*, 787 F.3d 851, 858 (7th Cir. 2015), and the "court should freely give leave when justice so requires"—not least when the parties stipulate, *see* Fed. R. Civ. P. 15(a)(2).

As written, the rules could prove terribly inefficient for counsel and clients if they were required to file an amended complaint, thereby triggering a new answer, just to perform the simple task of removing a claim or party that everyone agrees has turned out immaterial to the suit, not least forgetting the longstanding tradition of pursuing this relief in many federal courts facilely under Rule 41(a). The court deems this amendment (by deletion rather than interlineation) effectuated instanter through this order without need to file amended pleadings.

B. *Ms. Montgomery May Only Pursue a Single Product Liability Tort Claim under the IPLA Based on Failure to Warn and Design Defect Theories.*

No one argues a theory other than under Indiana law or identifies a conflict among state laws. *See McCoy v. Iberdrola Renewables, Inc.*, 760 F.3d 674, 684 (7th Cir. 2014); *Simon v. United States*, 805 N.E.2d 798, 805 (Ind. 2004). Ms. Montgomery underwent her implant surgery in Indiana and sustained any injury here. The court thus applies Indiana law. *See McCoy*, 760 F.3d at 684; *Porogi v. Ethicon, Inc.*, 2020 U.S. Dist. LEXIS 144374, 6-7 (N.D. Ind. Aug. 12, 2020).

The Indiana Products Liability Act (IPLA) governs all tort claims brought by a consumer against a manufacturer for physical harm caused by its product—regardless of legal theory. Ind. Code § 34-20-1-1; *see also Kennedy v. Guess, Inc.*, 806 N.E.2d 776, 779-80 (Ind. 2004); *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1007 (7th Cir. 2020). A manufacturer who places "into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer . . . is subject to liability for physical harm caused by that product[.]" Ind. Code § 34-20-2-1.

The IPLA recognizes three theories of liability. "A product may be defective under the IPLA if it is defectively designed, if it has a manufacturing flaw, or if it lacks adequate warnings about dangers associated with its use." *Brewer v. PACCAR, Inc.*, 124 N.E.3d 616, 621 (Ind. 2019); *accord Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.3d 953, 956 (Ind. 2018). By its express terms, and since the 1995 amendments, the IPLA grounds design defect and failure to warn theories in negligence terms—requiring a user or consumer to "establish that the manufacturer or seller failed to exercise reasonable

care under the circumstances in designing the product or in providing the warnings or instructions." Ind. Code § 34-20-2-2; *see also Campbell Hausfeld*, 109 N.E.3d at 957.

In contrast to these two theories, a manufacturing defect theory in Indiana remains grounded in strict liability in the true sense. A showing of negligence is not required. Ind. Code § 34-20-2-2; *see also Kaiser*, 947 F.3d at 1008; *Bayer Corp. v. Leach*, 153 N.E.3d 1168, 1179 (Ind. Ct. App. 2020). As with any IPLA theory of product liability, a user or consumer must establish that the product was in a "defective condition unreasonably dangerous" to her. Once established for a manufacturing defect theory, however, this standard applies though "the seller has exercised all reasonable care in the manufacture and preparation of the product[.]" Ind. Code § 34-20-2-2(1); *see also* Ind. Code § 34-20-2-1. Ms. Montgomery concedes her manufacturing defect theory.

Rather than a single IPLA claim, Ms. Montgomery articulates her design and warning theories over the course of four counts—negligence (count 1), failure to warn (count 3), defective product (count 4), and design defect (count 5). Indiana recognizes but one IPLA claim.

The design and warning theories sound in negligence, but the negligence count goes beyond the IPLA claim that remains. For instance, it includes manufacturing defect theories that have been voluntarily withdrawn. The court thus favors treating the negligence claim in count 1 (absent a manufacturing theory) and the failure to warn and design defect theories as stated in counts 3 and 5 as merged and representing a single IPLA claim. Though the complaint entitles the latter two "strict liability" claims, these labels may be disregarded in favor of their substance. *See Zurich Am. Ins. Co. v. Ocwen Fin. Corp.*, 990 F.3d 1073, 1080 (7th Cir. 2021). The overlay of these allegations leaves the dismissal of any one of these three individual counts imprecise in this particular case.

That said, any other negligence claim cannot proceed. The standard of care for this product liability tort action remains the IPLA because of Ms. Montgomery's status as a user or consumer *vis-à-vis* this product. *See Vaughn v. Daniels Co. (W. Va.), Inc.*, 841 N.E.2d 1133, 1144 (Ind. 2006). Under

these circumstances, "the legislature intended that the [IPLA] govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 975 (Ind. 2002) (citation omitted); *see also Vaughn*, 841 N.E.2d at 1144; *Kennedy*, 806 N.E.2d at 779-80; *Kaiser*, 947 F.3d at 1007-08; *see, e.g.*, *Taylor v. Monsanto Co.*, 150 F.3d 806, 808 (7th Cir. 1998), *overruled on other grounds*, *Hill v. Tangherlini*, 724 F.3d 965, 967 n.1 (7th Cir. 2013) ("no doctrinal distinction between the negligent and strict liability failure-to-warn actions"). The IPLA likewise disposes of the negligent infliction of emotional distress claim in count 10. *See Doerner v. Swisher Int'l, Inc.*, 272 F.3d 928, 932 (7th Cir. 2001).

The gross negligence claim (count 14) cannot survive. There are no degrees of negligence in Indiana. *South E. Ind. Nat. Gas Co., Inc. v. Ingram*, 617 N.E.2d 943, 953 (Ind. Ct. App. 1993). "The law imposes but one common law duty and that duty is to use due care." *Id.* As such, and particularly as adumbrated, the gross negligence claim is likewise subsumed within the IPLA. *See Vaughn*, 841 N.E.2d at 1144; *Stegemoller*, 767 N.E.2d at 975; *see also Fowler v. Werner Co.*, 2014 U.S. Dist. LEXIS 79174, 3 (N.D. Ind. June 10, 2014) (same conclusion).

Ms. Montgomery also pursues fraud-based claims—common law fraud (count 6), fraudulent concealment (count 7), and constructive fraud (count 8). She offers no defense in her summary judgment response why these claims too, being as they are based on representations about the product, aren't subsumed by the IPLA. They indeed are. *See Bayer Corp.*, 153 N.E.3d at 1189; *Ryan v. Philip Morris USA, Inc.*, 2006 U.S. Dist. LEXIS 9077, 9 (N.D. Ind. Feb. 22, 2006); *Ridgley v. Ethicon, Inc.*, 2017 U.S. Dist. LEXIS 17556, 6-7 (S.D.W.Va. Feb. 8, 2017). They are repackaged iterations of a failure to warn theory. They add nothing to the merged IPLA claim that remains here, so the court grants summary judgment on each count.

At this point, all that remains for consideration is the single IPLA claim represented by the failure to warn and design defect theories ensconced in counts 1, 3, and 5, as merged. The court grants summary judgment on the remaining counts, at least those not otherwise stipulated for dismissal.

C. *The Court Denies Summary Judgment on the IPLA Claim.*

1. *Failure to Warn.*

Dr. Perlmutter implanted Ms. Montgomery's TVT-O. Ethicon argues that Ms. Montgomery cannot establish a failure to warn because her physician already knew of the product's risks and never relied on the company's warnings in recommending treatment for Ms. Montgomery. These arguments address what product liability specialists often call "warnings causation" in the context of a sophisticated intermediary—whether, but for a defect in the warnings, the injury would not have occurred because the physician would have recommended a different course of action.

Under the IPLA, Ms. Montgomery must establish that the TVT-O caused her harm, that Ethicon sold the product in a defective condition unreasonably dangerous to her as a foreseeable user or consumer, that the company was in the business of selling the product, and that the product reached her in the condition in which it was sold. *See* Ind. Code § 34-20-2-1; *Bourne v. Marty Gilman, Inc.*, 452 F.3d 632, 635 (7th Cir. 2006). The argument today focuses on her burden to establish an unreasonably dangerous defective condition in the product that caused her harm.

To prove a defective condition from inadequate warnings, she must show Ethicon failed to exercise reasonable care in imparting warnings or instructions. *See* Ind. Code § 34-20-2-2. A product is defective if a seller fails to "properly package or label the product to give reasonable warnings" of the product's dangers or fails to "give reasonably complete instructions" on the product's proper use when "the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer." Ind. Code § 34-20-4-2.

The duty to warn users of potential dangers in a product is generally non-delegable, though Indiana recognizes an exception in its sophisticated intermediary doctrine. *See Nat. Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 163 (Ind. Ct. App. 1997); *First Nat'l Bank & Trust Corp. v. Am. Eurocopter Corp.*, 378 F.3d 682, 691 (7th Cir. 2004). This doctrine often appears in medical device cases, though it isn't limited to such. The doctrine applies when (1) the product is sold to an intermediary with knowledge or sophistication equal to that of the manufacturer, (2) the manufacturer adequately warns this intermediary, and (3) the manufacturer can reasonably rely on the intermediary to warn the ultimate consumer. *See Am. Eurocopter*, 378 F.3d at 691. A physician can be a learned intermediary.

In applying this doctrine, Indiana law requires consideration of the likelihood that harm will occur if the physician fails to pass the warning on to the ultimate consumer, the nature of the probable harm, the probability that a learned physician will pass on the warning, and the manufacturer's ease or burden of giving the warning directly to the consumer. *See Downs*, 685 N.E.2d at 163 (citation omitted). Reliance on a learned intermediary is only reasonable when "the intermediary knows or should know of the product's dangers." *Id.* at 164. This is nearly always a question of fact. *See id.*

"Under Indiana's learned-intermediary doctrine, a medical-device manufacturer can discharge this duty by providing adequate warnings to physicians," *Kaiser*, 947 F.3d at 1015, or pointing to information within the public domain, *see Downs*, 685 N.E.2d at 164. In such circumstances, the chain of causation breaks because the physician stands in the gap to communicate the risks to the patient. Thus, Ms. Montgomery must show not only that a manufacturer's warning was inadequate, but that "such inadequacy affected the prescribing physician's use of the product and thereby injured [her]." *Minisan v. Danek Med., Inc.*, 79 F. Supp.2d 970, 978-79 (N.D. Ind. 1999); *accord Porogi*, 2020 U.S. Dist. LEXIS 144374 at 11. She must show that different warnings would have caused her physician to recommend a different course of action. *See Kaiser*, 947 F.3d at 1016-17. This causation-in-fact inquiry often will prove a factual question for the jury too. *See Kovach v. Caligor Midwest*, 913 N.E.2d 193, 198

(Ind. 2009); *cf. Am. Eurocopter*, 378 F.3d at 691-92 (helicopter manufacturer not liable for failing to warn about the dangers of blade flap given the sophistication of trained pilots).

It is just so here. To be sure, Dr. Perlmutter testified that he knew that surgery with mesh had the potential to cause acute or chronic pain, vaginal scarring, infection, urinary frequency and urgency, dysuria, incontinence, organ or nerve damage, fistula formation, neuromuscular problems, and a host of other issues. He was aware of a foreign body response as a possible side effect. He was aware that erosion, exposure, or extrusion might occur, and that tissues might contract or shrink. He testified that the TVT-O had an acceptable risk profile and presented a safe and effective treatment for stress urinary incontinence in women.

That said, Dr. Perlmutter also testified that he was unfamiliar with the differences between Ethicon's laser-cut and mechanically-cut meshes. He said he would have liked to know that particle loss could result from mechanically-cut mesh. To that point, he would have recommended the laser-cut mesh based on its resistance to degradation, particle loss, and permanent narrowing. Nothing on this record thus indicates this physician knew of all risks—or increased risks perhaps—attendant to mechanically-cut mesh. He said chronic pain was expected to be "uncommon," but that he would have informed a patient like Ms. Montgomery that this risk was not uncommon if Ethicon had so advised him. He likewise would have shared the risk of nerve entrapment as common if Ethicon had advised him of its commonality. His testimony creates a genuine triable issue on causation vis-à-vis the learned intermediary doctrine. It cannot be said as a matter of law that Dr. Perlmutter knew of all risks from Ethicon to enable him to communicate them learnedly to his patient.

Ethicon also argues that Dr. Perlmutter never read or relied on Ethicon's warnings, so no change in their substance would have altered his recommendation to Ms. Montgomery. His testimony isn't so definitive. He learned during his residency how to implant the TVT-O. He readily admitted at the time of his deposition that he couldn't recall reviewing Ethicon's instructions for use (IFU), but

that he "probably did." When asked whether he relied on Ethicon's IFU, he explained that he would consider any information he had and pass along pertinent information to the patient. He said he may have seen Ethicon's IFU or may not have. Later, though he testified he probably had reviewed Ethicon's IFU, he seemed to pivot from his prior testimony to say he didn't rely on it.

The failure to read warnings may prevent a showing of causation. *See Deaton v. Robison*, 878 N.E.2d 499, 504 n.1 (Ind. Ct. App. 2007). If a person hasn't read the warnings, no change to them would effectuate a different result. They would remain unread and unmotivating, and thereby non-causative. But Indiana law recognizes a heeding presumption—that an alternate adequate warning would have been read and heeded, if only given. *See Cook v. Ford Motor Co.*, 913 N.E.2d 311, 326 n.8 (Ind. Ct. App. 2009) (failure to read *all* warnings wasn't fatal on causation); *Montgomery Ward & Co. v. Gregg*, 554 N.E.2d 1145, 1156 (Ind. Ct. App. 1990) (recognizing heeding presumption). This "presumption does not completely dispose of the causation issue in a failure-to-warn case," just "establish[es] that a warning would have been read and obeyed." *Kovach*, 913 N.E.2d at 199.

The heeding presumption applies with more force here when the record proves less than clear what Dr. Perlmutter once reviewed from Ethicon's instructions and whether he would have passed that information to his patient. His ambiguous testimony creates a genuine jury question. *See Shager v. Upjohn Co.,* 913 F.2d 398, 402 (7th Cir. 1990) ("the task of disambiguating ambiguous utterances is for trial, not for summary judgment"); *Jarrell v. Monsanto Co.*, 528 N.E.2d 1158, 1164 (Ind. Ct. App. 1988) ("failure to read them does not bar a claim as a matter of law"); *see, e.g., Ortho Pharm. Corp. v. Chapman*, 180 Ind. App. 33, 56 (Ind. Ct. App. 1979) (doctor consulted some but not all warnings concerning drugs, so causation was jury question). Ambiguous testimony from the implant surgeon and Indiana's heeding presumption preclude summary judgment on the failure to warn theory.

2. *Design Defect.*

Several jurisdictions require that a claimant establish a reasonable alternative design to prove a design defect theory, whether as an adoption of the Restatement (Third) of Torts § 2 or as a gloss on the Restatement (Second) of Torts § 402A on which many states have built their product liability law. The question today is whether Indiana law requires proof of a safer alternative design to maintain a design defect theory under the IPLA. The answer is no. *See Kaiser*, 947 F.3d at 1012-13; *TRW Vehicle Safety Sys., Inc. v. Moore*, 936 N.E.2d 201, 209, 214-16 (Ind. 2010).[1] The court thus denies the motion because this is Ethicon's sole argument for summary judgment on the design theory.

CONCLUSION

Accordingly, the court DISMISSES counts 2, 9, 11-13, and 15 in accordance with parties' amendment [ECF 94, 105], GRANTS the summary judgment motion on counts 1 (except as to the single IPLA claim), 4[2], 6-8, 10, and 14 [ECF 46], and DENIES the summary judgment motion on counts 1, 3, and 5 as to the single IPLA claim only, hereafter merged as one claim [ECF 46].

SO ORDERED.

October 20, 2021

s/ Damon R. Leichty
Judge, United States District Court

[1] *Kaiser* was issued after the motion was originally filed in the MDL.

[2] The court's original opinion omitted reference to count 4 in this conclusion, hence this amended opinion. This count is duplicative given the merged IPLA claim from counts 1, 3, and 5.